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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,529	05/09/2006	Samir F. Saba	UPITT-09379	7228

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
08/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,529	SABA, SAMIR F.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10,27-29,31,33-41,43 and 44* is/are pending in the application.

4a) Of the above claim(s) *6-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29,31 and 33-41, 43, 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/10 has been entered.

Election/Restrictions

Claims 6-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/16/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Having the implantable device configured to deliver the pacing burst to discriminate VT from SVT is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In order for the device to discriminate between VT and SVT, the device must first be configured to apply the simultaneous pacing burst (e.g. as seen on page 3, lines 5-10 of the specification) as without the pacing burst the device is unable to

discriminate VT from SVT. It is noted that all electrodes are "configured" to apply a pacing burst since an electrode is just a conductive piece of material that can apply a pacing burst and therefore setting forth that the electrodes can apply the burst does not actually have the system apply the burst.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: Having the implantable device configured to deliver the pacing burst to discriminate VT from SVT (see the above 112 first rejection).

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-29, 31, 33, 34, 36-41 and 44 are rejected under 35 U.S.C. 102(e) as anticipated by Kupper (6813518). Kupper discloses a pacemaker/defibrillator to deliver simultaneous pacing burst pulses to the atrium and ventricle when a tachycardia is detected (e.g. abstract, figures 6, 7, col. 11, line 53), using multiple leads/electrodes and thereafter senses for the first atrial or ventricular depolarization (e.g. col. 11, line 64, figure 3, element 74/58) to determine the first depolarization to provide different intervals (e.g. escape intervals, col. 10). Figure 5 shows a timing device as element 63 that is used to set the pacing escape intervals. These intervals are used to set pacing escape intervals (e.g. V-V, V-A, A-V, and A-A) for the different pacing modes and to determine arrhythmias and the device necessarily does determine the earliest arriving electrical signal and the location of origin (atrium or ventricle) since it sets the pacing intervals accordingly, since following therapy it waits to sense a ventricular or atrial event (e.g. cols 9-11). This sensing of the earliest arriving electrical signal meets the claimed limitation of the device "configured to discriminate between a supraventricular tachycardia and a ventricular tachycardia by determining if an earliest arriving electrical signal was detected by said atrial lead distal tip electrodes or said ventricular lead distal tip electrodes" since the claim only states it discriminates between the SVT or VT "**by** determining if said earliest arriving electrical signal was detected by said …tip electrodes" which the timing device of Kupper does. In other words, if you determine the earliest arriving electrical signal, you have identified the origin of an

arrhythmia since that is how the claim states the identification is done. NOTE, the claim does not state that the determination of the depolarization is used to "diagnose" an origin of an arrhythmia (i.e. "determining the earliest...signal; diagnosing between SVT and VT using said determined earliest signal"—this appears to have support on page any new limitation will require support in the specification). In addition, the leads of Kupper necessarily have separate conductors since they are separate leads and deliver signals and sense from separate electrodes.

Claims 35 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupper. Kupper discloses the claimed invention except for the quadripolar sensing lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Kupper, with the quadripolar sensing lead since it was known in the art and the examiner is taking official notice that IMDs use quadripolar sensing leads to provide the predictable results of allowing multiple areas of the heart to be sensed with one lead by inserting a minimal number of leads and therefore providing less trauma/problems to the heart.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The claims only state that the discrimination between VT and SVT is done "by determining" the earliest arriving signal. Therefore, if a piece of prior art determines the earliest arriving signal, it has discriminated between VT and SVT as set forth by the applicant's claim. As an example, a step/element to "discriminating between red rocks and green rocks in a bag by detecting if there are rocks in the bag" only requires detecting if there are rocks in the bag and not if they are actually red or green. It is suggested to go a step further in the claim and claim that there is a diagnosis between SVT

and VT using the detected earliest arriving signal (although, this new limitation will need to be further searched and considered). This diagnosis can be seen in the specification, such as on page 25.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571 272 4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
8/20/10